REMARKS/ARGUMENTS

Claims 1-22 have been canceled and new claims 25-32 have been added to more clearly define applicant's invention and distinguish it over the art of record.

Claims 23 and 24 stand withdrawn based on applicant's previous election in response to examiner's restriction requirement.

It is earnestly believed that the new claims overcome the rejections imposed by examiner against some of the now-canceled claims based on nonstatutory obviousness-type double patenting.

Applicant's invention is directed to an implantable device and device-implemented method for very early detection of CHF. To the extent the references applied by examiner pertain to CHF, the emphasis on early detection in the preceding sentence is quite significant, as is explained below. As applicant notes in the Summary, this invention stems from the recognition that specific structures of the device of applicant's prior '771 application (now US 6,829,503) that are dedicated to specific tasks, may share functions if the device is utilized or integrated with other diagnostic or therapeutic devices.

The references cited by examiner in the various art-based rejections (all of which are respectfully traversed insofar as they may be sought to be applied against the current claims) set forth in the Action against the now-canceled claims – namely, US 4,884,576 to Alt (Alt), US 6,600,949 to Turcott (Turcott), US 6,336,903 to Bardy (Bardy), and a purported combination of Alt with Turcott – are to be contrasted with applicant's invention as disclosed and claimed.

Alt's disclosure is directed to an invention that broadly provides a more reliable determination of a patient's individual physiological parameters and basic condition than had thertofore been available, for purposes of automatic adjustment of the pacing rate of an implanted artificial pacemaker to an optimum rate individually tailored to conditions of patent rest and physical exercise, and more specifically to tailor control of pacing rate to the individual patient's state of exercise and related respiratory rate. To that end, Alt established an algorithm for pacing control based on a relationship of respiratory rates (according to states of patient physiological activity and rest) to pacing rates, in which a sensor positioned in the right heart is used to measure impedance of blood in that region, representing such parameters

as rate and depth of respiration, contractility of the mycoardium, and stroke volume, among others, to control the rate at which stimulating pulses are generated by an implanted artificial cardiac pacemaker.

The Alt disclosure does not pertain to detection or treatment of congestive heart failure. And Alt's technique of sensing by electrodes positioned in the right heart of the patient to measure the blood impedance therein, and extrapolating to arrive at other parameters, is not related to the techniques or devices employed by applicant in the present invention as disclosed and claimed.

For example, nothing in the Alt disclosure teaches or suggests measuring local impedance of a portion of the patient's body generally occupied by the lungs solely through surface mounted electrodes on a device implanted subcutaneously in the patient's body at the locality where the impedance measurements are to be performed, in a method or device for early detection of congestive heart failure, as required by each of applicant's new claims 25-32, among other limitations.

Bardy's disclosure is directed to the use of trans-thoracic impedance as a physiological measure of pathophysiology indicative of congestive heart failure. This reference does not disclose or suggest a local impedance measurement of a type in which the electrodes are positioned outside the thoracic cage on a body-implantable device, or a method in which any impedance measurement obtained from a local impedance-derived signal is used in the monitoring of congestive heart failure. Rather, Bardy describes an external database with many inputs to evaluate the occurrence of heart failure by means of a sophisticated data recognition program.

Accordingly, Bardy, by itself or in any rational combination with any other of the references of record, neither teaches nor suggests impedance measurements made solely through surface mounted electrodes on an implantable device that is subcutaneously implanted (and, hence, located outside the thoracic cage), as recited in applicant's present claims.

Turcott describes a method for monitoring the condition of a heart failure patient by using an implantable or other ambulatory monitor to sense the patient's respiratory patterns, by which to identify a patient experiencing Cheyne-Stokes respiration. Cheyne-Stokes

respiration is a condition in which the patient undergoes an abnormal pattern of respiration characterized by alternating periods of apnea and deep rapid breathing, in up to about a 3-minute cycle from apnea to slow shallow breathing gradually progressing to the deep rapid breathing and returning to the shallow breathing and apnea, the latter period without respiration lasting up to about 20 seconds. Authoritative sources observe that the most common cause of an alteration in blood chemistry that might induce Cheyne-Stokes respiration is CHF, especially in elderly patients with degenerative arterial disease.

In one disclosed embodiment, Turcott detects mechanical changes of the thorax attributable to breathing, using an ultrasound transducer or an intrathoracic pressure transducer, to recognize hyperventilation and apnea. In another Turcott embodiment, changes in blood or tissue pH or CO.sub.2 concentration and partial pressure are detected to recognize the abnormal respiration pattern. Still another embodiment detects changes in pulse amplitude, or alternating loss and return of respiration-induced amplitude modulation, or pulse-interval variation, each of which is associated with Cheyne-Stokes respiration. And yet another embodiment monitors modulation of the average heart rate over time to detect its absence as an indication of Cheyne-Stokes respiration. This information is used to detect and alert its recipient of changes in the patient's condition warranting attention.

Contrary to the examiner's statement of rejection applying Turcott, the only references to location of the implant in the specification found by applicant is "a microphone diaphragm 30, part of the preferred embodiment of the sound sensor, is indicated by the dotted line in FIGS. 2c and 3c. ... [and] preferably placed such that it is directed toward the heart and lungs;" and in another place in the text, a statement that "an implantable hemodynamic monitor embodiment is configured for subcutaneous or submuscular implantation." The term "hemodynamic," of course, indicates blood circulation including cardiac function and peripheral vascular physiology.

An accelerometer is used by Turcott purely to trigger (or more accurately, according to the description, to suppress) a recording event. Data acquisition is set to take place periodically, e.g., hourly, provided the patient has been at rest for at least 10 minutes. If patient activity is detected by the accelerometer within the 10-minute window, data acquisition is suppressed until the next time the condition is satisfied. The accelerometer of

Turcott's disclosure is not used and is not suggested for use to control an artificial pacing rate.

With reference to an alternate embodiment for detecting pulmonary edema in conjunction with Cheyne-Stokes respiration, Turcott observes that pulmonary edema will cause a decrease in the baseline thoracic impedance. So far as can be determined from the description, impedance is used in one application of vascular plethysmography (detecting changes in the vessel's blood volume) which measures the heart pulse signal to detect changes in the autonomic nervous system balance. These are substantially the only references to impedance found by applicant in Turcott's entire disclosure.

It is emphasized that applicant discloses a device to detect the early occurrence of heart failure, which is not represented by pulmonary edema. Rather, this type of edema, which is a very rare condition, occurs at the end stage of sudden onset of a left ventricular failure. Patients with congestive heart failure are not typically admitted to a hospital for pulmonary edema, and pulmonary edema does not represent the typical condition that is found in congestive heart failure. As stated in applicant's "Background" section at pages 1 and 2 of applicant's specification, in pertinent part:

> "The present invention relates ... more particularly to an implantable device for detecting and monitoring the progression of congestive heart failure.
>
> "Many patients who have suffered one or more myocardial infarctions subsequently require treatment for congestive heart failure (CHF). The left heart fails while the pumping function of the right heart remains adequate, because the latter has only about 20% of the workload of the former. This leads to an increase in blood volume congested to the lungs, resulting in pulmonary congestion, build up of edema, and congestion of internal organs including the stomach and intestines. Increased fluid in the stomach and intestines reduce their ability to absorb drugs prescribed for treatment of CHF, particularly diuretics. The congestion is often accompanied by a worsening of myocardial function, with consequent drop in blood pressure and reduced renal perfusion, which only further aggravates the congestive situation. Thus, late recognition of congestion leads to increased dosages of oral diuretics that are unsuccessful to treat the condition, ultimately requiring that the patient be hospitalized.
>
> "Avoidance of hospitalization and the pitfalls of late treatment require detection of CHF at an early stage, so that the prescribed drugs can be fully absorbed and effective. If detected early, a combination of diuretics and other drugs can slow the progress of the disease and allow

the patient to enjoy an improved lifestyle." [Emphasis added].

And a bit later in applicant's "Background" section:

> "It is a principal aim of the present invention to provide an implantable heart failure monitor and ventilation measuring implant that constitutes an improvement over the device of the '771 application, capable of achieving very early detection of CHF." [Emphasis added]

The examiner has cited several specific portions of the text in the Turcott patent specification, presumably to buttress his position concerning what that document discloses as a purported anticipation of applicant's claims under rejection, namely:

Col. 8, line 55, which states that a patient alert provides notification to the patient;

Col. 9, line 4, which refers to QRS morphology in an ECG sensed using electrodes;

Col. 11, lines 29-32, which refer to alternate embodiments in which vascular plethysmography is performed with non-radiant methods, including mechanical strain, electrical impedance, and pressure;

Col. 13, lines 49-50, which states that an implantable hemodynamic monitor embodiment is configured for subcutaneous or submuscular implantation; and lines 58-61, which state that when the implanted monitor recognizes worsening disease status, the patient is notified, and data is telemetered via an external telemetry unit and via telephone lines to the physician or to a central location for further review;

Col. 14, lines 29-32, which state that in the preferred embodiment, one of the sensors is an accelerometer, whose output is used by the electronic circuit to condition data acquisition on the activity of the patient; and lines 49-61, which state:

> "Yet another alternative is the preferred embodiment, in which the electronic circuit includes a microprocessor used to derive a high-level clinical diagnosis from the collection of sensor outputs. For example, the electronic circuit might deduce that an acute heart failure exacerbation is developing and that the patient and physician should be notified. In this case the device would activate the patient alert 14 shown in FIG. 1 to inform the patient that medical attention should be sought. In the preferred embodiment, the alert is provided through an

> electromechanical transducer that generates sound and mechanical vibration, which instructs the patient to telemeter data from the implanted hemodynamic monitor to the physician or emergency room."

Col. 18, lines 45-54, which state:

> "In alternate embodiments, the presence of pulmonary edema is detected with more direct measures than lung sounds. Thoracic impedance and ultrasound are two specific alternate embodiments. In addition to the changes in respiratory pattern associated with the Cheyne-Stokes respiration of pulmonary edema, described below, which both of these signals can detect, pulmonary edema will cause changes in their baseline readings. Specifically, pulmonary edema will cause a decrease in the baseline thoracic impedance, and an increase in reflected ultrasound signal from the lung fields."

These cited passages either have no applicability to the current claims of this application, or are discussed and distinguished above relative to applicant's invention as claimed.

Accordingly, Turcott neither teaches nor suggests "measuring local impedance of a portion of the patient's body generally occupied by the lungs solely through surface mounted electrodes on the device with the device implanted subcutaneously in the patient's body at the locality where the impedance measurements are to be performed, determining when the local impedance measurements are indicative of a condition of congestive heart failure other than from the existence of a state of edema of the patient," as required among the limitations of claim 25 and its dependent claims 26-30, or a substantially similar set of limitations of claim 31, or "for exposing said electrodes to tissue in a portion of the patient's body generally occupied by the lungs, said circuit module including circuitry that measures local impedance of said body portion through said surface mounted electrodes and determines when the impedance measurements are indicative of a condition of congestive heart failure wherein the determination of congestive heart failure is based on factors other than the existence of edema of the patient" as recited in device claim 32.

It is therefore respectfully submitted that new claims 25-32 are patentable over the references of record.

In view of the foregoing amendments and remarks, applicant submits that this application is in condition for allowance. Such favorable action is most earnestly solicited. If examiner finds that any issue or issues remain as a barrier to such allowance, he is respectfully invited to call applicant's attorney at the phone number listed below for the purpose of expediting the removal of such issue or issues.

Respectfully submitted,

ECKHARD ALT

Donald R. Greene
Registration No. 22470
Customer No. 53164
Post Office Box 6238
Goodyear, AZ 85338
Telephone: 623-327-9771
Facsimile: 623-327-9778

Dated: 08/21/2006

DRG/ACRAMD08R2006TO1STOA.050